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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/291,347 04/14/99 HANAK

J CACO-0051

EXAMINER

HM22/1003

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ART UNIT

PAPER NUMBER

1652

DATE MAILED:

10/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/291,347

Applicant(s)
Hanak et al.

Examiner
Peter Tung

Group Art Unit
1652



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-35 is/are pending in the application.

Of the above, claim(s) 19-35 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-18 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-18, drawn to a method of preparing RNA-free cellular components, classified in class 435, subclass 91.1.
 - II. Claims 19-33, drawn to a transformed host cell that produces an RNase and compositions comprising said host cell, classified in class 435, subclass 252.3.
 - III. Claims 34 and 35, drawn to pharmaceutical compositions comprising RNA-free cellular components, classified in class 514, subclass 1.

2. The inventions are distinct, each from the other because of the following reasons:

Each of Groups II and III is directed to a separate and distinct invention. Group II is directed to a transformed host cell that produces recombinant DNA, recombinant protein or recombinant carbohydrate and an RNase and compositions comprising said host cell and Group III is directed toward pharmaceutical compositions comprising RNA-free cellular components.

The products of Group II and III would be expected to have distinct morphological, functional, chemical and physical properties as indicated by their divergent classification, process of making and process of using. These products are capable of separate manufacture, use, or sale as claimed, and are patentably distinct.

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3. Inventions of Group I and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by another process such as by purification using ion exchange columns.
4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
6. During a telephone conversation with Ms. Doreen Trujillo on a provisional election was made with traverse to prosecute the invention of Group I, claims 1-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 19-35 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

8. Acknowledgment is made of applicant's claim for foreign priority based on applications filed in the United Kingdom on 4/14/1998 and 8/6/1998. It is noted, however, that applicant has not filed a certified copy of the United Kingdom applications as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 1 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: and isolating said RNA-free cellular component.

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12. Claims 2 and 3 recite the limitation "the RNase". There is insufficient antecedent basis for this limitation in the claim. Claim 1, from which claims 2 and 3 depend upon, recites "RNase activity".

13. Claim 3 recites the limitation "said cells in the medium other than said cells producing the cellular component" in claim 3. There is insufficient antecedent basis for this limitation in the claim. No other source of cells is provided in the independent claim 1.

14. Claims 4-18 are unclear as to the relationship between culturing and lysing cells producing the cellular component and culturing and lysing cell producing an RNase. Replacement of the "and" between the phrases "cellular component and culturing" and "lysing cell producing an RNase" with "with" overcome this rejection.

15. Claims 8-18 recites the limitation "the gene encoding" in claim 8. There is insufficient antecedent basis for this limitation in the claim.

16. Claims 8, 9 and 11-18 recites the limitation "said RNase". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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18. Claims 1-12, 14-16, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhu et al. With regard to claims 1-3, 5, 7, 9, 10 and 18, Zhu et al. teach (page 3147, "Results," 1st paragraph; Table 1) a method comprising culturing cells constitutively expressing recombinant RNase I and lysing said cells. The cellular lysate comprises cellular components and RNase with sufficient activity to degrade all the RNA molecules present in the cell lysate.

With regard to claims 4 and 6, Zhu et al. teaches (page 3147, Table 1) culturing and lysing bacteria encoding RNase I and bacteria not encoding RNase I.

With regard to claim 8, Zhu et al. also teach (page 3147, column 2, paragraphs 2 and 3) that DNA encoding RNase I is integrated into chromosomal DNA.

With regard to claim 11 and 14, constitutive production of RNase I is indicative that the cell is producing RNase in a regulated manner.

With regard to claim 12, Zhu et al. teach (page 3147, column 2, 2nd paragraph) that RNase I is overproduced by the cell.

With regard to claims 15 and 16, Zhu et al. teach (page 3149, column 1, last paragraph to column 2, 1st paragraph; Table 3) that the RNase is secreted out of the cytoplasm and into the periplasm of the bacteria.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu et al. as applied to claims 1, 11, 15 and 16 above, and further in view of Clare et al. The teachings of Zhu et al. have been discussed supra. Zhu et al. further teach a plasmid comprising DNA encoding RNase I. Claims 13 and 17 add the further limitation of inducible production of RNase and secretion of the RNase in the medium, respectively. Zhu et al. do not teach inducible production of RNase or secretion of RNase into the medium. Clare et al. teach (page 208, Table I) inducible production of protein in yeast where the yeast is secreted into the medium. Clare et al. teach (page 206-207, "Results and Discussion," part (a)) plasmids which allow secretion production of proteins in yeast. Protein production is under the control of an inducible promoter when this plasmid is integrated in the appropriate yeast host. Clare et al. further teach (page 208, Table I) comparison of protein secreted into the medium and protein contained in the cells by lysis of yeast

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cells expressing heterologous protein. Clare et al. do not teach secretion production of RNase I or inducible production of RNase I. It would have been obvious to one of ordinary skill in the art at the time the invention was made to express RNase I in yeast by secretion into the medium under inducible control and to lyse the cells for the benefits of secretion production of RNase I, inducible production of RNase I, and measurement of the amount of RNase I secreted into the medium. One of ordinary skill in the art is motivated to combine the two references as Clare et al. teach (page 206, column 2, 2nd paragraph, lines 11-20) that the yeast secretion expression system is a general system which can be used for the secretion production of foreign proteins and Zhu et al. provide the teaching of DNA encoding RNase I. One of ordinary skill in the art would have a reasonable expectation of success at doing this as the inducible secretion expression of heterologous proteins in yeast is well known in the art and it would be a reasonable expectation to be able to express the RNase I, according to the teachings of Zhu et al., in the yeast system as taught by Clare et al. Therefore the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

21. No claims are allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to be 'PAC', with a long horizontal line extending to the right.

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600